

Remarks

Claims 1 and 15 are amended herein. Claims 10-11 and 27 are canceled herein, without prejudice to renewal. Following entry of this amendment, claims 1, 3-4, 6, 12-17, and 26 are pending.

Claim 1 has been amended to incorporate the limitations of claim 11. In addition, support for the amendments of claim 1 can be found throughout the specification, specifically at page 7, lines 4-6, page 9, lines 6-15, page 10, lines 1-7 and page 11, lines 24-30. Support for the amendment of claim 15 can be found throughout the specification, specifically at page 23, lines 3-12, page 24, lines 18-25, page 32, lines 10-23.

No new matter is added. Reconsideration of the subject application is respectfully requested.

Telephone Interviews

Applicants thank the Examiner for the helpful telephone conferences with their representative on March 28, 2005 and March 29, 2005, wherein allowable subject matter and claim amendments were discussed. As discussed with Examiner Ton, the present amendment is submitted to place the claims in condition for allowance.

Restriction Requirement

Claim 27 was withdrawn from consideration, as allegedly being drawn to a separate invention. Applicants respectfully traverse the restriction requirement, and submit that the Min genetic background could easily be searched with all of the claims to transgenic mice. However,

solely to advance prosecution, claim 27 is canceled herein. Applicants reserve the right to pursue this subject matter in a divisional or continuation application.

Rejections Under 35 U.S.C. § 112

Claims 1, 3, 4, 6, 10-17 and 26 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly there is not sufficient written description for transgenic mice including a transgene comprising a degenerate variant of SEQ ID NO: 1 (although there is sufficient description for transgenic mice including a transgene encoding NOX 1). Claims 10 and 11 are canceled herein, rendering the rejection moot as applied to these claims.

Applicants respectfully disagree with this rejection as applied to claims 1, 3, 4, 6, 12-17 and 26. Applicants note that, given basic knowledge about the genetic code and the guidance provided by the specification (for example, see the specification at page 7, lines 4-6, page 9, lines 6-15, page 10, lines 1-7 and page 11, lines 24-30), there is adequate written description in the specification for one of skill in the art to produce degenerate variants of SEQ ID NO: 1 (which encodes NOX 1). However, solely to advance prosecution, claim 1 has been amended to recite that the transgene encodes SEQ ID NO: 2 (NOX 1), as discussed with Examiner Ton. Applicants submit that this amendment removes the rejection.

Claims 1, 3, 4, 6, 10-17 and 26 were rejected under 35 U.S.C. § 112, first paragraph, as the specification, while enabling for transgenic mice wherein the genome comprises a transgene encoding NOX 1, is allegedly not enabling for transgenic mice, the “nucleated cells” of which comprise a transgene encoding NOX1. In addition, claims 1, 3, 4, 6, 10-17 and 26 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly the metes and bounds of “nucleated cells”

are not defined. Applicants respectfully disagree with these rejections, as “nucleated cells” is readily understood to mean cells including a nucleus. However, solely to advance prosecution, claim 1 has been amended to remove the term “nucleated cells,” and to recite a transgenic mouse whose genome comprises a transgene encoding NOX1. Applicants submit that the amendment of claim 1 removes these rejections.

The Office action further asserts that the specification is not enabling for methods of identifying agents for use in treating inflammation or colon cancer. Applicants respectfully disagree with this rejection.

Applicants submit that ample evidence is presented in the specification that the claimed transgenic mice exhibit hyperplasia of colonic epithelial cells, and thus can be used to identify agents that are of use in treating colon cancer or inflammation. Indeed, the Office action notes that the specification is enabling for transgenic mice whose genome comprises a transgene encoding NOX1, operably linked to the CX1 promoter, and the use of these mice, as the mice show a phenotype of increased overgrowth of colonic epithelial cells when exposed to pathogenic bacteria. However, solely to advance prosecution, claim 15 has been amended to be generically directed to a method for identifying agents of use in treating hyperplasia of colonic epithelial cells, as discussed with Examiner Ton. Applicants submit that this amendment overcomes the rejection.

The Office action states that the specification is enabling for transgenic mice whose genome comprises a transgene encoding NOX 1 operably linked the CX1 promoter, but alleges that the specification is not enabling for transgenic mice whose genome comprises a transgene

including another promoter (substituted for CX1). Applicants respectfully disagree with this rejection.

Applicants submit that the production of transgenic mice, and the use of any promoter in a transgene, is enabled by the specification. Expression vectors for the production of transgenic mice and promoters of use are described in the specification, for example at page 12, line 25 to page 16, line 2. Moreover, one of skill in the art can readily identify promoters of use.

However, solely to advance prosecution, claim 1 has been amended to incorporate the limitations of claims 11, and now recites that the promoter is the CX1 promoter. Applicants submit that the amendment of claim 1 renders the rejection moot.


Conclusion

It is respectfully submitted that the present claims are in condition for allowance, which action is requested. If any additional matters remain to be addressed before a Notice of Allowance is issued, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below for an additional interview.

Respectfully submitted,

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